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M/S PCT
Attorney Docket No. 12480-000069/US

IN THE U.S. PATENT AND TRADEMARK OFFICE

APPLICANT(S): Shunichi **KURODA** et al. CONF. NO.: 1324
APPL NO.: 10/509,252 FILED: September 28, 2004
INT'L APPL.: PCT/JP03/02600 FILED: March 5, 2003
ENTITLED: **DRUGS FOR TREATING HEPATIC DISEASES WITH THE
USE OF HOLLOW PROTEIN NANOPARTICLES**

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS
UNDER 35 U.S.C. § 371**

July 25, 2005

M/S PCT
Commissioner for Patents
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. § 371 in the United States Designated/Elected Office (DO/EO/US) ("Notice") dated May 25, 2005 for the above-identified patent application, please consider the remarks below.

Under the provisions of 37 C.F.R. § 1.494 or 37 C.F.R. § 1.495, attached hereto are the following additional items necessary for entering the national phase in connection with the above-identified PCT international application.

- ☒ Executed Declaration and Power of Attorney (photocopy).
- ☒ Attached is a copy of Form PCT/DO/EO/905.

REMARKS

Favorable reconsideration of this application in light of the following remarks is respectfully requested.

No claims having been cancelled or added, the Applicants respectfully submit that claims 1-7 remain properly under consideration in this application.

Sequence Listing(s)

It is asserted that the “application clearly fails to comply with the requirements” of 37 C.F.R. § 1.821 *et seq.* Notice at page 2. The Applicants respectfully traverse this assertion.

The Applicants note that the requirements of 37 C.F.R. § 1.821 *et seq.* are implicated only where the specification, claims and/or drawings include:

(a) Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an ***unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides***. . . .

* * *

(b) ***Patent applications which contain disclosures of nucleotide and/or amino acid sequences, in accordance with the definition in paragraph (a) of this section***, shall, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, conform exclusively to the requirements of §§ 1.821 through 1.825.

37 C.F.R. § 1.821(a)-(b) (emphasis added).

The Applicants respectfully submit that the present application includes ***no such disclosure of sequences of amino acids or nucleotides*** and is not, therefore, subject to

the requirements of 37 C.F.R. § 1.821 *et seq.* The Applicants' representative also contacted the USPTO sequence help desk to confirm the understanding that a reference to or an identification of a "gene" or a "protein" does not trigger a requirement that a corresponding nucleotide sequence or amino acid sequence be generated and provided.

The Applicants' respectfully maintain, therefore, that no Sequence Listing is required for this application and request that this requirement be withdrawn.

CONCLUSION

In view of the above remarks, the Applicants respectfully submit that each of the requirements identified in the Notice has been addressed and either satisfied or overcome, leaving the present application in condition for allowance. A notice to that effect is respectfully requested.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

The Applicants submit that no extension fee is required because the undersigned has filed the documents within the allotted time given by the Notification of Missing Requirements (Form PCT/DO/EO/905). However, if for some reason it is determined that an extension of time is necessary, applicant hereby respectfully petitions for an appropriate extension of time for the timely filing of the present paper in accordance with the provisions of 37 C.F.R. § 1.136 and 37 C.F.R. § 1.17.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge any underpayment or non-payment of any fees required under 37


C.F.R. §§ 1.16 or 1.17, or credit any overpayment of such fees, to Deposit Account

No. 08-0750, including, in particular, extension of time fees.

☒ A check in the amount of \$130.00 is attached hereto to cover the increase
in fees of the filing Surcharge is enclosed.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

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